Food and Drug Administration

Center for Biologics Evaluation and Research
Meeting of the Blood Products Advisory Committee
Great Room, Building 31
FDA White Oak Campus
10903 New Hampshire Avenue
Silver Spring, MD 20993

May 13, 2015

Draft Agenda		
Time	**Presentation**	**Presenter**
8:00 a.m.	Call to Order and Opening Remarks Introduction of Committee	Brooks Jackson, M.D., MBA Chair, BPAC
	Conflict of Interest Statement	Bryan Emery, LCDR Designated Federal Officer, BPAC
Topic I: **Strategies for Implementation of Serological and Nucleic Acid Testing for *Babesia microti* in Blood Donors**		
8:10 a.m.	Introduction and Background	Sanjai Kumar, Ph.D. OBRR, FDA (15')
8:25 a.m.	Epidemiology of Babesiosis, including Transfusion-Associated Infection	Barbara Herwaldt, M.D. CDC (30')
8:55 a.m.	Considerations in Transfusion Transmitted *Babesia microti*	Jeffrey McCullough, M.D. University of Minnesota (20')
9:15 a.m.	Risk of Babesia Infection in United States Blood Donors	Mikhail Menis, Pharm.D., M.S. OBE, FDA (10')
	Benefit-Risk Assessment for Testing Blood Donations for *B. microti*	Richard Forshee, Ph.D. OBE, FDA (30')
	Questions for Speakers (5')	
10:00 a.m.	BREAK (15')	
10:15 a.m.	Experiences with Investigational Testing of Blood Donors for *B. microti*	
	Investigational Blood Donor Screening for Babesia microti: Implications For Blood Safety	Susan Stramer, Ph.D. American Red Cross for Imugen (35')
	Screening with an Investigational Enzyme Immunoassay for Babesia microti Evaluated in an IND Study on U.S. Blood Donor Populations	Andrew Levin, Ph.D. Immunetics, Inc. (25')
11:15 a.m.	Considerations for Testing Blood Donations for *B. microti*	Sanjai Kumar, Ph.D. OBRR, FDA (20')
11:35 a.m.	Questions for Speakers (5')	
11:40 a.m.	Open Public Hearing (40')	
12:20 p.m.	Break (10')	
12:30 p.m.	Open Committee Discussion Questions for the Committee (60')	

Time	Presentation	Presenter
1:30 p.m.	Lunch (45')	
Committee Updates:		
2:15 p.m.	Considerations for Hemoglobin S Testing in Blood Donors	Orieji Illoh, M.D. OBRR, FDA (15')
2:30 p.m.	Considerations for a Revised Blood Donor Deferral Policy for Men Who Have Sex with Men	Alan Williams, M.D. OBRR, FDA (15')
2:45 p.m.	Break	
Topic II: Review of the Research Programs in the Laboratory of Cellular Hematology, Division of Hematology, OBRR		
3:00 p.m.	Overview of CBER Research Programs	Carolyn Wilson, Ph.D. CBER, FDA (10')
3:10 p.m.	Overview of OBRR Research Programs	CD Atreya, Ph.D. OBRR, FDA (10')
3:20 p.m.	Overview of the Division of Hematology Research Program	Basil Golding, M.D. OBRR, FDA (10')
3:30 p.m.	Overview of the Laboratory of Cellular Hematology	Jaroslav Vostal, M.D. OBRR, FDA (45')
4:15 p.m.	Questions for the Speakers (15')	
4:30 p.m.	Open Public Hearing (30')	
5:00 p.m.	Closed Committee Discussion (30')	
5:30 p.m.	Adjournment	